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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,278	09/30/2002	Jeffrey C. Leung	013341.000021	5691
24239 7590 04/23/2008 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709				
EXAMINER				
ERIZO, DARWIN P				
ART UNIT		PAPER NUMBER		
3773				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/065,278

Applicant(s)

LEUNG ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-31, 35, 37-78 and 85-152 is/are pending in the application.
- 4a) Of the above claim(s) 21-31, 35-54, 67-78 and 85-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20, 55-66 and 141-152 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/07 has been entered.

Specification/Drawings

2. The amendment filed 11/19/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The new proposed drawings contain new matter as the original specification did not specify that the barbs projected from flat sides of the polygonal sutures, it would not be inherent from the original disclosure that what is shown in the proposed drawings would have been the only orientation that the barbs would take. For example, the barbs could project from a location on the suture body where two sides intersect.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-20, 55-66 and 141-152 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 17, 18, 141, 142 and 143 have been amended to recite the limitation of "wherein each successive barb is offset from the previous barb relative to the longitudinal axis of the body such that any plane perpendicular to the body and cutting transversely through the body and intersecting any portion of a barb will not intersect any portion of any other barb on the body". The applicant pointed out the support is to be found in Fig. 7A. However, Fig. 7A is insufficient to provide support for the new limitation.

It is noted that the written description for Fig. 7A (paragraph [0137]) does not provide teaching for the barbed suture having a plane that is perpendicular to the body and cutting transversely through the body and intersection any portion of a barb will not intersect any portion of any other barb on the body. This limitation is also not inherent in the drawing provided for Fig. 7A and contradicts any other figure in the specification. It is also noted that the drawings are not stated to be drawn to scale. It is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue. However, the description of the article pictured can be relied on, in

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combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. In re Wright, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Furthermore, Fig. 7A does not provide any support for the above recited limitation in combination with the suture having a spirality angle.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 17-20,141-144,147 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,123,077 to Alcamo in view of US 5,123,911 to Granger, and in further view of US 5,269,783 to Sander et al.

Alcamo discloses a barbed suture with helically positioned barbs. However, the ratio of the suture diameter to needle diameter is not disclosed. Additionally, the barbs being in a twist cut multiple spiral disposition is not disclosed. However, the examiner notes that the twist cut is really a product-by-process limitation. Once the cuts are made after the suture has been twisted, the suture is unwound. The resulting pattern of the cuts is merely a multiple spiral. Since Alcamo discloses a suture with barbs which are in multiple spirals, this limitation is met. As for the specific spirality angle, as these were afforded no particular significance in the specification, were not disclosed as solving any particular problem or being for any particular purpose, the examiner contends that such angles would be obvious design choices, as the applicant's invention would work equally as well with the undisclosed spirality angle of the Alcamo's barbs.

Granger discloses that it was known to attach sutures to suturing needles; wherein the diameter of the needle is equal to the diameter of the suture. This ratio would fall within the claimed ratio. It would have been obvious to have attached the barbed suture of Alcamo to an equal diameter suture needle, in order to facilitate the attachment process and to produce a stronger suture/needle combination which can easily traverse through tissue. As for the range of the ratio being between 3:1 to about

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1.47:1, the applicant failed to disclose that the lower limit being 1.47:1 was in any way critical, and did not solve any particular problem or solve any particular purpose relative to ratios between 1.47:1 and 1:1. Ganger indicated that normally the needle diameter would be larger than that of the suture and therefore, ratios above 1:1 were disclosed, however, what the exact ratio is was not disclosed. The examiner contends that one would have assumed that a ratio of about 1.47:1 would have produced a similar result to that of around 1:1 and therefore this lower limit on the range would have been considered an obvious design choice.

Sander discloses a barbed suture in Fig. 1, wherein it appears that the barbed suture has successive barb that is offset from the previous barb relative to the longitudinal axis of the body such that any plane perpendicular to the body and cutting transversely through the body and intersecting any portion of a barb will not intersect any portion of any other barb on the body. As such, these type of arrangement is just another variant known in the art. Therefore, one of ordinary skill in the art would have found it obvious to modify the device of Alcamo to have the arrangement disclosed by Sander because a simple substitution of one known barb configuration for another known barb configuration will obtain predictable results and would be a mere obvious design choice. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

9. Claims 55-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo in view of Granger and Sander, as applied above, and further in view of US 5,931,855 to Buncke.

Alcamo as modified by Granger/Sander makes obvious the invention as claimed with the exception of the suture materials. Buncke, discloses the claimed suture materials. It would have been obvious to have made the Alcamo/Granger/Sander suture out of the suture materials disclosed by Buncke, as these materials to tailor the suture to the procedure... e.g. for certain procedures, it would be desirable for the suture to be non-absorbable and others it would be more desirable for the sutures to be absorbable.

10. Claims 17-20,55-66,141-144,147 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,931,855 to Buncke in view of 5,123,911 to Granger and in further view of US 5,269,783 to Sander et al.

Buncke discloses a barbed suture with helically positioned barbs. The suture is formed of absorbable or non-absorbable material. However, the ratio of the suture diameter to needle diameter is not disclosed. Additionally, the barbs being in a twist cut multiple spiral disposition is not disclosed. However, the examiner notes that the twist cut is really a product-by-process limitation. Once the cuts are made after the suture has been twisted, the suture is unwound. The resulting pattern of the cuts is merely a multiple spiral. Since Buncke discloses a suture with barbs which are in multiple spirals, this limitation is met. As for the specific spirality angle, as these were afforded no particular significance in the specification, were not disclosed as solving any particular problem or being for any particular purpose, the examiner contends that such angles would be obvious design choices, as the applicant's invention would work equally as well with the undisclosed spirality angle of the Buncke's barbs.

Granger discloses that it was known to attach sutures to suturing needles; wherein the diameter of the needle is equal to the diameter of the suture. This ratio would fall within the claimed ratio. It would have been obvious to have attached the barbed suture of Buncke to an equal diameter suture needle, in order to facilitate the attachment process and to produce a stronger suture/needle combination which can easily traverse through tissue.

Sander discloses a barbed suture in Fig. 1, wherein it appears that the barbed suture has successive barb that is offset from the previous barb relative to the longitudinal axis of the body such that any plane perpendicular to the body and cutting transversely through the body and intersecting any portion of a barb will not intersect any portion of any other barb on the body. As such, these type of arrangement is just another variant known in the art. Therefore, one of ordinary skill in the art would have found it obvious to modify the device of Buncke to have the arrangement disclosed by Sander because a simple substitution of one known barb configuration for another known barb configuration will obtain predictable results and would be a mere obvious design choice. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

As for the range of the ratio being between 3:1 to about 1.47:1, the applicant failed to disclose that the lower limit being 1.47:1 was in any way critical, and did not solve any particular problem or solve any particular purpose relative to ratios between 1.47:1 and 1:1. Granger indicated that normally the needle diameter would be larger than that of the suture and therefore, ratios above 1:1 were disclosed, however, what

the exact ratio is was not disclosed. The examiner contends that one would have assumed that a ratio of about 1.47:1 would have produced a similar result to that of around 1:1 and therefore this lower limit on the range would have been considered an obvious design choice.

11. Claims 145,146,148,149,151 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo/Granger/Sander (or Buncke/Granger/Sander), as applied to the claims above, and further in view of US 3,918,455 to Coplan.

Alcamo or Buncke as modified by Granger/Sander make obvious the invention as claimed with the exception of the suture cross-sectional shape being non-round. Coplan discloses that it was known to manufacture sutures to have other shaped sutures. It would have been a mere obvious design choice to have manufactured the sutures of Alcamo or Buncke as modified by Granger/Sander in a non-round shape as taught by Coplan.

Response to Arguments

12. Applicant's arguments with respect to claims 17-20, 55-66 and 141-152 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773